

EPA Region 9 Response to Comments on Clear Creek Management Area RMP / EIS

Responses to Mark Van Baalen 1 Mar 10

Comment 1: *No amphibole previously detected in New Idria Basin*

Response: By using activity-based sampling, EPA collected air samples which represented exposures over a large geographic area, in comparison to soil samples collected from discrete locations. The air samples were analyzed by Transmission Electron Microscopy, which permitted the identification of fiber mineralogy. Amphiboles were identified in 8% percent of the samples. It is not uncommon for both chrysotile and amphibole asbestos to be found in the same general locations. "...Chrysotile occurs most commonly in serpentinites and serpentinized ultramafic rocks but may also occur in altered or metamorphosed mafic rocks or in metamorphosed carbonate rocks. The amphibole asbestos minerals (tremolite, actinolite, anthophyllite, riebeckite, and cummingtonite-grunerite) also occur in and immediately adjacent to serpentinites and serpentinized ultramafic rocks and in a variety of other metamorphosed rocks..." John P. Clendenen and Ronald K. Churchill. **Geology of naturally occurring asbestos in California; Geological Society of America, Cordilleran Section, 101st annual meeting; American Association of Petroleum Geologists, Pacific Section, 80th annual meeting** Abstracts with Programs – Geological Society of America, Vol. 37, No. 4, Apr 2005, pp. 37.

Responses to California Department of Parks and Recreation OHMV Recreation Division 19 Apr 10

Comment 1: *The significance and accuracy of the information presented in the Health Risk Assessment is open to debate (Page 2 of 5).*

Response: EPA Region 9 used standard and accepted practices for environmental asbestos sample collection, sample analysis, and risk assessment. The EPA Risk Assessment for CCMA was reviewed by members of the Agency's Technical Working Group for Asbestos, the California Department of Toxic Substances Control (DTSC), and the California Office of Environmental Health Hazard Assessment (OEHHA). EPA reviewers and both California agencies agreed with and support Region 9's methods and findings. Domestic and international health and scientific organizations, including the State of California, the EPA, the Centers for Disease Control, the National Toxicology Program, the National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), the World Health Organization International Agency for Research on Cancer, and the International Program on Chemical Safety, have all classified chrysotile asbestos as a known human carcinogen.

Comment 2: *The OHMV Division quotes some of the uncertainty language in the Risk Assessment and concludes: "Decisions based on such variable and imprecise studies should be cautiously and conservatively implemented, if at all." (Page 3 of 5)*

Response: It appears that the commenter is confusing uncertainty related to Risk Assessment with variability and imprecision. The caveats and uncertainties discussed in the EPA risk assessment are included in the report to notify the reader of the bounds to the estimates. The actuarial data is not in question. Disease and death result from

asbestos exposures, and the variability presented is only in the magnitude of the cancer effect and the possible range of estimates. In fact, the EPA findings were consistent with previous exposure studies conducted at CCMA. Full disclosure of the uncertainties is standard in Risk Assessments and does not invalidate the overall finding that the asbestos exposures at CCMA, and the attendant risks, are significant.

Comment 3: *The Division believes serious questions have been raised about the Health Risk Assessment, such as identification and differentiation of chrysotile and amphibole asbestos, asbestos-related epidemiology, appropriateness of risk models, and activity based sampling methods.*

Response: Activity-based sampling has been used for decades to measure exposures in occupational environments and is currently the standard practice for environmental exposures to asbestos. The sampling methods used at CCMA were based on discussions of typical uses that EPA had with BLM rangers and members of the OHV community. The ability of the Transmission Electron Microscopy (TEM) method used for the air sample analysis to differentiate between amphibole and chrysotile asbestos is well established and the occurrence of both types of asbestos is not unexpected (See response to Mark Van Baalen Comment 1 above). Both the EPA and California OEHHA toxicity values were used to demonstrate the range of possible quantitative estimates. The toxicity values are based on the same dose response studies but EPA's toxicity value is a mean of the dose and the OEHHA value is based on the more health protective upper confidence limit. While there is some debate within the scientific community regarding the varying potencies of the different types of asbestos relative to certain cancers, there is no debate that all types of asbestos cause cancer and debilitating and fatal non-cancer disease.

Responses to Friends of Clear Creek Management Area

Comment 1: *The samples used by EPA for the Risk Assessment are skewed toward the dry season, and the Risk Assessment therefore does not represent "typical" CCMA user situations. The samples do not reflect the distribution anticipated in the Sampling and Analysis Plan.*

Response: The Sampling and Analysis Plan charts for the number of samples to be collected at CCMA only included the three days of sampling conducted in November 2004. It was not intended to represent the total samples collected or the seasonal distribution. In totality, EPA conducted sampling over 9 days from September 2004 to September 2005. Five of the 9 days were during the winter months, representing moist and wet conditions. All the sampling was conducted under conditions that are applicable to time periods when CCMA is open. Of the sample results used in the Risk Assessment, approximately 50% were from dry sampling days and the remaining 50% were from moist and wet sampling days. As the attached chart below shows, the EPA results for the dry season and the wet or "open" season are comparable. There was no significant difference in the concentrations between dry and wet exposures. Therefore, regardless of the weighting, EPA believes that the data used in the Risk Assessment were indicative of typical use scenarios.

Comparison of Mean and 95% UCL for All Data and Only Winter Open Season Data - Riding Positions

Position	No. Valid Data - All/Winter	No. Detected Data - All/Winter	All Mean	Winter Mean	Difference	Ratio Winter to All Mean	All UCL	Winter UCL	Difference	Ratio Winter to All UCL
Adult Lead	41/20	35/17	0.0673	0.0554	0.0119	0.8232	0.1040	0.1010	-0.0030	0.9712
Adult First Trailing	37/20	34/17	0.2480	0.2720	-0.024	1.0968	0.3940	0.3300	-0.0640	0.8376
Adult Second Trailing	17/10	16/9	0.5630	0.4800	0.083	0.8526	1.0790	1.2720	0.1930	1.1789
Child Lead	36/17	33/14	0.0991	0.0971	0.002	0.9798	0.1660	0.1960	0.0300	1.1807
Child First Trailing	31/14	31/14	0.3830	0.4760	-0.093	1.2428	0.5950	1.7570	1.162	2.9529
Child Second Trailing	17/10	17/10	0.5410	0.4880	0.053	0.9020	0.6730	0.6770	0.0040	1.0059

Comment 2: *The results are “atypical” of actual use conditions because photographs taken during the EPA sampling events show that the BLM graded the road prior to the sampling to increase dust production and asbestos exposure levels.*

Response: The photographs were taken at the beginning and end of one of the sampling events as the riders were returning to the staging station at the Oak Flat campground.

With the exception of the SUV driving/riding scenario, the road riding was only a portion of the total route and therefore only a portion of the exposures measured. It is representative of typical CCMA activity that riders start from the Oak Flat campground and travel on the road a short distance to access the trails. Sampling on the road was minimized for those riders whose air pumps had timed-out before returning to the staging area. EPA has no information to indicate that road conditions were not typical of usual CCMA conditions.

Responses to Curt McDowell, Save Clear Creek, 5Mar 2010

Comment 15: *The exposure durations and visits per year do not represent typical CCMA use patterns.*

Response: The visits per year actually came from the 1992 PTI Health Risk Assessment and are based on national recreational survey data and statements of CCMA users. The 30-year exposure duration is standard for recreational exposures per the EPA Risk Assessment Guidance for Superfund. Further, many CCMA users have stated that they have been riding at CCMA for more than 30 years. The risk numbers were expressed in ranges to provide information that users could adjust to their personal exposure experience.

Comment 16: *The most frequent users of CCMA ride solo or in the lead position. If this was taken into account in the risk calculations, the Assessment would be more accurate and the numbers would be significantly lower.*

Response: The concentrations measured for lead riders are lower than those measured for trailing riders and solo riding would therefore have a lower excess lifetime cancer risk. The risk estimation for workers used lead rider data only. EPA used lead and first and second trailing exposures in the analysis because it was believed that group riding more closely represents actual CCMA use conditions.

Comment 17: *The air samplers ran continuously and collected samples when the rider was encountering a dust cloud. In actual practice, a rider would avoid or hold his/her breath when traversing a dust cloud. Therefore, the sampling method caused overestimation of actual asbestos exposure.*

Response: The sampling pumps do not totally mimic human breathing behavior. The exposures EPA measured can overestimate or underestimate actual individual exposures. That is one reason why EPA uses a range of mean and upper confidence limit concentrations.

Comment 18: *The exposure measurement did not take into account the precautions BLM publishes for riding at CCMA, i.e. “If riding an OHV in a group, spread out along the trail, and don’t ride in another rider’s dust.”*

Response: The sample collection was designed to capture typical exposures. Avoiding dust would reduce the exposure to trailing riders and the overall risk of asbestos-related disease.

Comment 19: *The Risk Assessment overestimates the speed, distance, and time-spent while riding at CCMA.*

Response: Certainly if someone spends an hour riding, the exposure will be less than someone who rides for 6 hours. The risk factors for an individual may be less or more than those shown in the Risk Assessment, based on individual riding practices and exposures.

Comment 20: *Applying the adjustments noted in Comments 15 through 19 results in revised risk numbers that are within EPA's acceptable risk range.*

Response: Any change in concentration and duration of exposure will change the estimated risk. The EPA risk estimations reflect assumptions about exposure and duration in the context of standard EPA risk assessment methodology.

Comment 21: *The OEHHA toxicity value was used in the Risk Assessment and predicts disease in the rider population. Since exposures have occurred for decades and no one has shown disease, the OEHHA value is inapplicable and should not be used.*

Response: There are no studies of the rider populations to prove or disprove the assertion that there has not been any asbestos-related disease. In fact, a study conducted at the University of California, Davis, and published in the Journal of Respiratory and Critical Care Medicine in 2005, found that residential proximity to naturally-occurring asbestos is significantly associated with increased risk of mesothelioma in California (*American Journal of Respiratory and Critical Care Medicine* Vol 172. pp. 1019-1025, (2005) © 2005 American Thoracic Society, doi: 10.1164/rccm.200412-1731OC, **Residential Proximity to Naturally Occurring Asbestos and Mesothelioma Risk in California** Xue-lei Pan, Howard W. Day, Wei Wang, Laurel A. Beckett and Marc B. Schenker)

Inclusion of the OEHAA value was intended to provide the public with information on the risk range that could be estimated based on the measured exposures. It is entirely appropriate for use in assessing risks at CCMA because CCMA is located in California and the OEHHA toxicity value is the State of California value for asbestos exposure. As with all toxicity values, it is a standard risk model that does not predict individual outcomes, and therefore may or may not reflect disease rates in specific populations.

Responses to Don Amador, Blue Ribbon Coalition 4 Mar 10

Science Issue 4: *The Risk Assessment is flawed because trailing riders rode in the dust cloud of the lead rider.*

Response: See Curt McDowell above - Response to Comment 18

Science Issue 5: *The Risk Assessment is flawed because riders spent too much time on Clear Creek Road.*

Response: With the exception of the SUV exposure sampling, riding was done primarily on trails selected with the input of BLM field rangers and CCMA motorcycle and ATV riders. Road riding was only from the staging areas to the trail access points, which would approximate the routes taken by CCMA users.

Science Issue 6: *The Risk Assessment sampling routes do not simulate a typical CCMA off-highway vehicle experience.*

Response: See Response to Science Issue 5 above.

Science Issue 7: *Un-supervised test riders may have ridden off the prescribed course.*

Response: EPA riders followed the approximate courses for the sampling, considering individual variation for trail conditions. EPA believes that the samples are representative of exposures from riding within CCMA.

Science Issue 10: *The sampling is not representative of typical use conditions because most riding at CCMA takes place in the winter.*

Response: See Friends of Clear Creek Management Area – Response to Comment 1

Science Issue 11: *Modification of Test Protocol*

Response: This comment is addressed in the Risk Assessment in Section 4.1.5 on Page 4-6.

Response to Don Amador e-mail 3 Mar 2010

Comment page 3 of 4: *The EPA Risk Assessment is flawed because most of the samples were collected during the dry periods when the CCMA is closed.*

Response: When EPA started the sampling, the CCMA was not closed during the dry periods. The interim closure was instituted by BLM in response to our sampling results. Summer riding was an acceptable practice during the EPA study design. For further discussion on the distribution of sampling, please see Response to Friends of Clear Creek Management Area Comment 1.

Comment page 3 of 4: *The EPA Risk Assessment used inaccurate speed information for the riding scenarios.*

Response: The estimated speeds were derived by approximating the area covered and dividing by the time the sampler was on the trails. The concentration of asbestos found in the breathing zone during the rides is the important information.

Comment page 4 of 4: *The DEIS is fatally flawed because it ignored the scientific work in progress at the EPA's Office of Solid Waste and Emergency Response to create a new risk analysis methodology for chrysotile since there is a growing body of scientific opinion that chrysotile is not a significant public health risk.*

Response: In 2008, EPA requested that the external Science Advisory Board (SAB) review an approach to address toxicities from various mineral forms of asbestos. The objective of the proposed approach was to investigate the influence of asbestos mineral types and fiber dimensions on estimates of cancer potency derived from epidemiological

data. The Board agreed that mineral type and dimension are important determinants of asbestos toxicity, and that an effort to examine the relative contributions of these characteristics to asbestos toxicity was worth pursuing. However, the Committee found that the available exposure data was not robust enough to support the effort EPA proposed. In light of the Board's concerns, the EPA Office of Solid Waste and Emergency Response decided not to pursue the effort.

The effort to examine the toxicity of various asbestos mineral forms and dimensions was in no way predicated on scientific evidence that chrysotile asbestos is benign. On the contrary, the evidence continues to support EPA's position that chrysotile is a known human carcinogen and causes debilitating and fatal non-cancer disease. The serious health impacts of chrysotile exposure are recognized by the Centers for Disease Control, the Occupational Safety and Health Administration, the National Institute of Occupational Safety and Health, the World Health Organization International Agency for Research on Cancer, and others. Recent follow-up studies of North Carolina textile workers confirmed the strong relationship between estimated exposure to chrysotile and mortality from lung cancer and asbestosis. M. Hein, L. Stayner, E. Lehman, J. Dement. *Follow-up study of chrysotile textile workers: cohort mortality and exposure-response* *Occup Environ Med* 2007; **64**:616-625 doi: 10.1136/oem.2006.031005. Additional studies of the textile workers confirmed "that workers exposed to chrysotile are at increased risk of mesothelioma, as well as lung cancer." Loomis D, Dement JM, Wolf SH, Richardson DB. *Lung Cancer Mortality and Fiber Exposures among North Carolina Asbestos Textile Workers*, *Occupational and Environmental Medicine*, published online March 11, 2009 by the BMJ Publishing Group Ltd.

Comments of Amy Granat, California Association of 4 Wheel Drive Clubs, Inc. 12 Apr 2010

Comment 4: *The exposures measured by EPA were atypical for motorized use at CCMA.*

Response: Please see responses to Friends of Clear Creek Management Area Comment 1 and Comment 2, Curt McDowell Comment 16, Don Amador Science Issue 10.

Comment 5: *Data from the dry season must be removed from the DEIS because all alternatives include CCMA closure during that period.*

Response: See responses to Friends of Clear Creek Comment 1 and Don Amador e-mail Comment page 3 of 4.

Comments of Moore Smith Buxton & Turke 5 Mar 2010

There were no specific comments noted that require an individual EPA response

Comments of Salinas Ramblers Motorcycle Club 5 Mar 2010

Comment Risk to Children page 5: *Children ride ahead of their parents, and the EPA sampling had children riding behind.*

Response: EPA collected samples in the child breathing zone for lead and for trailing riders, so the child lead data can be used to reflect instances where the child rides ahead. For a child in the lead position, the mean exposure concentration for all events was

0.0991 f/cc and the 95% upper confidence limit (UCL) concentration was 0.1660 f/cc. The mean and UCL concentrations for adult lead riders was 0.0673 f/cc and 0.1040 f/cc respectively. This is consistent with the finding that child concentrations exceeded the paired adult concentration 64% of the time.

Comment EPA Report page 5: *The EPA sampling was not representative of typical CCMA use conditions.*

Response: Please see responses to Friends of Clear Creek Management Area Comment 1 and Comment 2, Curt McDowell Comments 16 and 18, Don Amador Science Issues 5 and 10, and Don Amador e-mail Comment page 3 of 4.

Comments of Ed Tobin 5 Mar 2010

Comment 3: *The EPA report is flawed because it did not simulate typical CCMA use scenarios.*

Response: Please see responses to Friends of Clear Creek Management Area Comment 1 and Comment 2, Curt McDowell Comments 16 and 18, Don Amador Science Issues 5 and 10, and Don Amador e-mail Comment page 3 of 4.

Comment 12: *"Uncertainty related to the toxicity parameters of the risk characterization includes the application of the IRIS and OEHHA asbestos toxicity values, which were developed from epidemiological studies of occupational exposures, to infrequent and episodic recreational exposures" should be corrected to read "Uncertainty related to the toxicity parameters of the risk characterization includes the application of the IRIS and OEHHA asbestos toxicity values, which were developed from epidemiological studies of occupational exposures, NOT to infrequent and episodic recreational exposures."*

Response: The wording in the Risk Assessment is correct as originally written. The IRIS value is based on occupational exposures which EPA is extrapolating to recreational exposures. The extrapolation is an uncertainty related to the risk estimations.

Comment 13: *The BLM has failed to inform the public that, since 2003, the EPA Office of Solid Waste and Emergency Response (OSWER) has been working on the creation of a new risk analysis methodology for chrysotile and that the growing body of opinion in the scientific community is that chrysotile is far less potent in causing disease than amphiboles. One such document discussing this subject is a paper that accompanies a November 2008 letter addressed to the EPA Administrator from the SAB Asbestos Committee on the subject: SAB Consultation on EPA Proposed Approach for Estimation of Bin-Specific Cancer Potency Factors for Inhalation Exposure to Asbestos. (Attached)*

Response: As a matter of policy, EPA strives to use the best and most recent science in its decision-making. The Agency has evaluated ways to improve the risk characterization for asbestos, but the efforts are not predicated on the belief that chrysotile exposure is not a public health concern. Please see response to Don Amador e-mail Comment page 4 of 4

Comment 22: *All of the actinolite and tremolite fibers found during sampling were found ONLY in the samples collected in September 2005.*

Response: This is not true. Amphibole fibers were found in air samples from the range of sampling events.

Comment 30: *The BLM and the EPA failed to advise the public in either the EPA Report or the DEIS that an EPA safety officer approved the use of N95 rated masks inside the helmets of EPA motorcycle riders (e-mail from Daniel Stralka, EPA dated Feb. 25 2010). "The riders with the full face helmets used N95 filter masks. They are not certified for asbestos use under OSHA but because of the safety concerns about the physical hazards and the 95 % efficiency for particulate removal the safety and health officer considered these an appropriate combination."*

Response: It is correct that the motorcycle riders used N95-rated face masks to reduce the dust inhalation. For these sampling events, the riders used helmets with face guards, and the typical respirators did not fit under this type of helmet. For the limited sampling period of the event, the 95% particulate efficiency was balanced with the physical safety concerns of the full face mask helmets. All other activities used full respirators.

Response to Martin Markham, Timekeepers Motorcycle Club 3 Mar 2010

Comment: *Mr. Markham attaches a list of documents regarding chrysotile exposure.*

Response: EPA is aware of the documents that are attached. While there is debate in the scientific community regarding the mode of asbestos toxicity, there is no debate among health experts and agencies that chrysotile asbestos exposure causes cancer and non-cancer disease. Please see response to Don Amador e-mail Comment page 4 of 4.

Response to James Strenfel, LAO Timekeepers MC, 28 Feb 2010

Comment Response 2: *The e-mail "...from Rick Cooper to Arnold Den and Jere Johnson of the EPA casts serious doubts about the scientific accuracy of the EPA report. Rick Cooper writes that the EPA has been consistent in mentioning that the risks could be much lower and perhaps zero. When the final EPA risk assessment was released, the words "and perhaps zero", were omitted."*

Response: The original language in the draft Risk Assessment said:

"Uncertainty related to the toxicity parameters of the risk assessment includes the application of the IRIS and OEHHA asbestos toxicity models, which were developed from epidemiological studies of occupational exposures, to infrequent and episodic recreational exposures. This uncertainty could mean that the actual risks could be much lower than those estimated in the CCMA assessment and perhaps zero. Another uncertainty, adjustments for early-lifetime childhood exposures, could mean that the actual risks are higher than those estimated in the report."

All risk assessments contain a discussion of the uncertainties inherent in the risk estimation and the effect that those uncertainties may have on overestimating or underestimating the actual risk. Theoretically, at the extreme end of the spectrum, the uncertainties related to the factors which go into an assessment of risk could be such that the assessment predicts a risk where an actual risk does not exist. This was recognized,

for example, in the EPA Guidelines for Carcinogen Risk Assessment (Federal Register Vol.51, No. 185, September 24, 1986, pages 33992-34003), which states in the discussion of the use of a particular procedure to predict cancer: "Such an estimate, however, does not necessarily give a realistic prediction of the risk. The true value of the risk is unknown, and may be as low as zero. The range of risks, defined by the upper limit given by the chosen model and the lower limit which may be as low as zero, should be explicitly stated." So the terms "as low as zero" or "perhaps zero" are used to describe the far end of the risk range for assessments with large uncertainties.

In the case of the CCMA Risk Assessment, the phrase "perhaps zero" was carried over as a standard expression of the uncertainty inherent in risk assessment. When Rick Cooper pointed out its inclusion, EPA realized that the phrase was not applicable to the assessment of the risk posed by the asbestos exposure at CCMA, and the phrase was removed. In fact, EPA believes that the risk detailed in the CCMA Assessment is significant and of concern.

The exposure and risk information used in the CCMA Assessment has less uncertainty than the information used in many assessments. The exposure data was comprised of asbestos concentrations in the breathing zone during actual CCMA activities, not hypothetical exposures extrapolated from general sampling of environmental media. Further, the EPA Integrated Risk Information System (IRIS) toxicity value for asbestos is derived from epidemiological studies of human fatalities and health effects, not from studies of test animals in the laboratory. Of the 14 epidemiological studies used to derive the asbestos toxicity value, 7 involve 100% chrysotile or predominately chrysotile exposures. While the risk assessment does not predict individual outcomes, there is more confidence that adverse health effects in humans is associated with increased exposure to asbestos.

In addition, the Superfund National Contingency Plan states that "For known and suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response." The EPA IRIS toxicity value for asbestos is actually a mid-line lifetime cancer risk value, not an upper bound value, so it already leans to an uncertainty that underestimates risk, making the "perhaps zero" statement even less applicable. The upper bound risk would more closely match the risk estimations of the California Office of Environmental Health Hazard Assessment (OEHHA).

It is also important to note the following language from the Risk Assessment:

"This risk evaluation assesses only the excess cancer risk from exposure to asbestos at the CCMA. It is known that asbestos causes diseases other than cancer, such as respiratory and pleural disease. The non-cancer effects are not quantitatively taken into account in this assessment, but could actually be more significant to total disease outcome from CCMA asbestos exposure. **Therefore,**

the general probability of developing disease from exposure related to activities at Clear Creek may be significantly underestimated in this report. “

This information additionally supports the inappropriateness of including the “perhaps zero” statement of uncertainty in the CCMA assessment report.

Response to Timekeepers Motorcycle Club 10 Mar 2010

Comment 1: *EPA omitted important studies from the derivation of the URF for asbestos and admitted such in their 1992 report on CCMA.*

Response: EPA was not involved in the 1992 report. It was done by the consulting firm PTI for BLM, and EPA had no input on the URFs derived by PTI. The EPA toxicity factor for asbestos is based on the review of 14 epidemiological studies of asbestos-related disease and death and combines risks from both lung cancer and Mesothelioma. The URFs derived in the 1992 PTI report are flawed and do not combine both endpoints.

Comment 2: *The commenter questions the risks of asbestos exposure at CCMA because amphibole is the fiber type that causes disease.*

Response: Please see Response to James Strenfel Comment 2 and Response to Don Amador Comment page 4 of 4.

Response to Terry Pederson, Timekeepers Motorcycle Club

Comment 6: *“The peer reviewed scientific studies indicate that Chrsotile [sic] has never been proven to cause disease, and in fact may be benign.”*

Response: This comment is not true. Please see Response to James Strenfel Comment 2 and Response to Don Amador Comment page 4 of 4.

Response to Randall Johnson

Note: Significant effort by the reviewer to understand the uncertainties in the evaluation and quantitatively estimate the effects are appreciated and the following responses are given to his detailed comments.

Comment 1: *EPA CCMA Asbestos Exposure and Human Health Risk Assessment 2008 (EPA 2008) does not provide significant new information relative to actual human risk and instead merely provides yet another analysis of exposures to CCMA users. Inclusion of “significant new information” found in EPA 2008 as a Need for Draft Clear Creek Management Area Resource Management Plan & Environmental Impact Statement, November 2009 (BLM 2009) is unjustified.*

Response: Previous asbestos exposure information for off-road motorcyclists in CCMA was collected in 1978 (Cooper & Popendorf, et al 1979, Popendorf & Wenk, 1983) and in the early 1990’s (PTI Environmental 1992). The EPA Risk Assessment Report collected additional exposure information at two different breathing heights for motorcycling and for several other activities that are common in the Management Area but were not previously assessed. EPA analyzed the collected fibers by Transmission Electron

Microscopy (TEM) following the International Organization for Standardization ISO 10321 (ISO 1995) protocols, the currently accepted standard. These additional activity-based samplings allowed for an up-to-date, more holistic determination of possible exposures associated with combined activity scenarios, and provide significant new and complete information about the magnitude of exposures associated with current CCMA activities. All the studies that have been conducted conclude that high dust-generating activities within the CCMA Area of Critical Environmental Concern (ACEC) result in increased exposure to asbestos.

Comment 2: *DOI employee occupational monitoring had lower exposures.*

Response: DOI employee monitoring has also demonstrated increased exposure during dust-generating activities within the Area of Critical Environmental Concern (ACEC). Rangers' activities were determined to be best represented as lead riders in the 2008 EPA risk assessment, and a risk analysis for this activity scenario was requested by BLM. The appropriate exposure scenario and resulting risks are presented in the Risk Assessment in Figures 10 and 11. The analytical method used in the occupational assessment was Phase Contrast Microscopy (PCM). This is the standard analytical method for measuring occupational exposures, but it cannot discern smaller fibers with widths <0.25 µm and does not distinguish asbestos from non-asbestos fibers. The TEM method used by EPA has the resolution to measure a wider range of fiber sizes and distinguish asbestos fibers from non-asbestos fibrous material. However, only the PCM equivalent asbestos fibers (PCMe) were used in the quantitative assessment of risk because those are the fiber sizes that were used to measure exposure in the epidemiological studies of the health outcomes of asbestos exposure. Additionally, in this study EPA followed the 1986 World Health Organization (WHO) recommendation to use a width limit of 3 µm diameter as a limit of respirability. This modification is particularly applicable to the situation at CCMA due to the unrefined nature of the asbestos exposure. Large blocks or "chunks" were seen in previous studies (W.C. Cooper et. al. 1979) and were present in EPA's TEM analysis of the fiber dimensions. These large pieces would add to the PCMe counts using the older PCM method fiber definition, but would not be respirable and therefore would not add to the fraction that makes it into the lung.

It is important to remember that fiber counts are being used as a surrogate measure of toxicity. In more recent TEM analysis of previous occupational PCM epidemiologic studies, all fiber dimensions - PCM, PCMe or other size fractions - correlate with disease; some more so than others and varying based on the exposure measured. (L.T Stayner, et al. Occupational Environmental Medicine 20 Dec 2007, D. Loomis, et al., ibid 5 November 2009) This is part of the continuing scientific effort to find the best indicator of exposure that correlates to health outcomes.

Comment 3: *The "mill and mining" cohorts were excluded from EPA's unit slope factor.*

Response: The commenter correctly points out that in the derivation of the Unit Risk Factor (URF) for cancer from airborne asbestos (US EPA 1986), the milling and mining cohorts were not included. When EPA was reviewing the occupational studies that form the basis for the URF, positive correlations between fiber counts and cancer outcomes were observed for mining and milling cohorts, as well as for cohorts of other industries

(textile production, insulation production, and installation and production of cement products). However, the milling and mining studies showed lower asbestos cancer potencies than those observed in other industries. This was thought to be due to differences in fiber size distribution between the industrial environments. The analytical method used at the time to measure exposures produced fiber counts that included fibers that were too large to reach the deep areas of the lung. Mining and milling exposures were logically thought to include a greater proportion of large blocky fibers that would not be respirable (EPA 1986). Inclusion of these nonrespirable fibers in the exposure estimates would dilute the apparent potency of respirable fibers present, thus artificially lowering the potency reported for the mining and milling cohorts (EPA 1986). Therefore, the URF is based on studies of processed materials where it was believed there was a lower proportion of nonrespirable fibers. These studies then more closely follow the exposure and response linkage manifested in the epidemiological studies. Large blocky fibers or “chunks” were seen in previous studies at CCMA (W.C. Cooper et al Science, 1979, vol. 209, pgs 685-8) and were present in EPA’s TEM analysis of the fiber dimensions. In the EPA Risk Assessment, the definition of PCMe included a width definition of < 3 um that eliminated the thick fibers, as recommended by the WHO 1986. Therefore, the PCMe counts in the EPA study represent likely respirable fibers, and as such it is appropriate to apply the EPA URF to the EPA data for the CCMA.

Comment 4: *EPA used sampling techniques that had been used at the site previously, but let the trailing riders ride in the dust of the rider ahead.*

Response: The commenter is correct that the classic industrial hygiene method of using a filter cassette placed in the breathing zone of the individual where air is sampled at a known rate was used in all the studies of activity based exposure at CCMA (W.C. Cooper et al 1979, Poperdorf and Wenk, 1983, PTI 1992, US EPA 2008). This demonstrates the usefulness of this procedure in assessing a wide range of activities. W.C. Cooper first reported a difference in the lead and trailing riders’ exposure in 1978. The US EPA 2008 report reproduced this result as illustrated in Figure 6 and Table G-4. It may be true that the riders in this study rode closer to the previous rider without experiencing a “mouthful of dust” because of their respiratory protection. However, group ride events are common among the activities at CCMA and the level of exposure would be increased in trailing riders. Table G-4 suggests as much as 10 fold higher with some degree of variability but still an increase in exposure.

Comment 5: *Analytical methods and PCM vs PCMe comparison.*

Response: The commenter is correct that TEM measurements of fibers are different than PCM measures. The attributes of TEM - better resolution, ability to distinguish asbestos from non-asbestos structures, and standard international counting / annotation protocols - are an improvement over the previous PCM methods. Even though TEM provides additional refinement of the fiber size distribution, only PCM equivalent fibers were used in the risk evaluation. Additionally, in this study EPA followed the WHO 1986 recommendation to use a width limit of 3 um diameter as a limit of respirability. This would have the effect of reducing the fiber count, compared to only a fiber length and aspect ratio determination. Several authors have investigated the correlation of PCM and TEM-PCMe fiber counts (C.Y. Hwang and Z.M. Wang, 1983 Archives of Environmental

Health, vol. 38, pgs 5-10, and more recently, L.T Stayner, et al. Occupational Environmental Medicine 20 Dec 2007, D. Loomis, et al., Occupational Environmental Medicine, 5 November 2009). PCM and TEM-PCMe fiber counts are well correlated with correlation coefficients of about 0.9. Even PTI, using the 10 samples which were analyzed by both techniques, had a correlation coefficient of 0.92. It must be kept in mind that fiber counts are only being used as a surrogate of toxicity. All fiber dimensions correlate with disease outcomes, but science is still seeking the best definition of that surrogate. Currently, the PCMe fiber counts are the measure by which exposure is determined.

Comment 6: *Amphibole fibers were detected.*

Response: EPA did find amphibole asbestos in the activity-based samples. The Agency currently makes no distinction of asbestos toxicity based on the form of asbestos. Asbestos is a natural mineral whose mineralogy is defined by the presence of minor amounts of other metals in the crystal structure. Please see Mark Van Baalen above - Response to Comment 1.

Comment 7: *EPA's conclusion that children are of special concern is not supported by the data.*

Response: As illustrated in Figure 8 of the Risk Assessment, exposure measurements in child breathing zones closer to the source of the dust generation resulted in higher fiber counts. These increased exposures were incorporated into the risk assessment for the appropriate scenarios where children were recreating at the CCMA. The increased exposure resulted in increased risks. Additionally, there is still significant discussion in the medical community as to the physiological differences in the child lung that may make a child more sensitive to particulate exposures. EPA's Particulate Matter Air Quality Criteria Document (2004), a consensus document which evaluated the state of the science for particulate inhalation, concluded that there are models and supporting experimental evidence that predict significant differences in particulates depositing in the child and adult lung, and that this may have irreversible effects on the developing lung. This is another uncertainty not quantitatively included in the risk assessment. Also, with respect to asbestos exposure, there is a latency period from time of first exposure to the manifestation of disease. The latency period may or may not be different between children and adults, but the longer life expectancy for children and the probability that a child will live long enough to express disease is increased and proportional to the extent and duration of exposure. Therefore, the combination of increased concentrations of asbestos measured in the child breathing zone, and the fact that the exposures are occurring early in life, lead EPA to the conclusion that children are of special concern.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street
San Francisco, CA 94105

July 30, 2010

Mr. Rick Cooper, Field Manager
Hollister Field Office
Bureau of Land Management
20 Hamilton Court
Hollister, CA 95023

Dear Mr. Cooper:

Enclosed are EPA Region 9's responses to comments received on the BLM Resource Management Plan and Draft Environmental Impact Statement for the Clear Creek Management Area that concerned the EPA Clear Creek Management Area Asbestos Exposure and Human Health Risk Assessment. The comments are organized by commenter and specific comment. Please do not hesitate to contact me at 415-972-3094 or johnson.jere@epa.gov if you have any questions or need clarification.

Sincerely,

A handwritten signature in black ink, appearing to read "Jere Johnson", is positioned above the printed name.

Jere Johnson
Remedial Project Manager

Enclosure

Cc Jeanne Geselbracht, EPA